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Deepankar Chatterjee

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SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
SUITE 800  
WASHINGTON, DC 20037

EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



### **Detailed Action**

Applicant's election with traverse of Group I, Claims 1-12 in the reply filed on 2/13/06 is acknowledged. The traversal is on the ground(s) that the claims of Groups I and II are so inextricably interrelated that a search of one invention would be co-extensive with a search of the other and hence said search would not be burdensome. Additionally, applicant argues that the fees involved in filing, paying issue and maintenance fees, etc. for an additional divisional application would be high. This is not found persuasive because a search of the promoter/expression system of Group I would not be co-extensive with a search of a method for preparing a high-throughput screening system and developing inhibitors against mycobacteria under low carbon conditions because a search for the promoter/expression system of Group I (a composition) does not require a search for intended uses of the composition. A separate search of the methodology recited in Group II would be required if Group II was to be rejoined with Group I. With regard to arguments that the restriction should be withdrawn because the fees required to file and prosecute a divisional patent application are, in applicant's view, high, it is noted that this type of argument cannot overcome a proper requirement for restriction. It is also noted that if the composition of Group I is eventually found allowable, the restriction requirement will be withdrawn and the claims of Group II (process of using) may be rejoined (See restriction requirement mailed 1/11/06).

The requirement is still deemed proper and is therefore made FINAL.

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Claims 13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/13/06.

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed promoter having the sequence of SEQ ID NO:2 is not recited as isolated or recombinant, is claimed using the open language "having" and hence reads on the promoter sequence as it occurs in nature.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by  
Fleischman et al.

Applicants claim a promoter having the sequence of SEQ ID NO:2.  
Fleischman et al. (US Patent 6,294,328, see whole document, particularly SEQ ID NO :2) teaches the same sequence (see also attached Sequence search results).  
Fleischman et al. therefore teaches the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 4 are vague because they do not appear to be written in proper idiomatic English. For example, an article such as “the” or the term “said” is required before the word “promoter”. “2.5 folds” should be “2.5 fold”.

Claim 3 (and dependent claims) are vague because it does not appear to be written in proper idiomatic English. Specifically the phrase “...said system comprising of promoter of 200 bp having SEQ ID No.2 in a vector pSAK12.” is confusing. The vector pSAK12 contains the promoter consisting of SEQ ID NO:2; however, the claim language reads on any promoter of 200 bp having (open language) SEQ ID NO:2 in the pSAK12 vector. It is unclear if applicants are claiming an expression system comprising the pSAK12 vector or the pSAK12 vector containing an additional promoter of 200 bp having SEQ ID NO:2.

Claims 5 and 6 are vague in that applicants recite an expression system with a carbon source and then recite that glucose is in the range of about 2.5 to 0.001% or about 2 to 0.02%. The claim language makes it unclear whether the expression system has a carbon source **and** has glucose in the recited concentrations or whether glucose is the carbon source.

Claims 7-12 are vague in that it is unclear what the relationship between the expression system recited (the vector pSAK12 containing the promoter of SEQ ID NO:2) and the growth of mycobacteria **in the presence of the promoter** is. It is unclear whether the mycobacteria are transformed with the pSAK12 vector because the genome of the mycobacteria species *Mycobacteria tuberculosis* naturally has the promoter represented by SEQ ID NO:2.

Claims 7-12 are vague in that applicants recite growth of mycobacteria in the presence of 0.02% glucose and then recite "i.e. under starved conditions". Since "starved conditions" encompasses conditions other than 0.02% glucose concentration, it is unclear what conditions applicants are claiming. The metes and bounds of the claimed subject matter are therefore unclear.

Claims 7-12 are vague in the absence of articles at appropriate positions in the claims. For example, in claim 7, "the" should be inserted prior to "percentage inhibition", "the" should be inserted prior to the phrase "presence of the promoter", etc.

Claim 12 is vague because it depends from itself.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.


Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
April 27, 2006

  
DAVID GUZO  
PRIMARY EXAMINER